


at least one polymer.

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B1
ent 15. A method of treating bacterial infections in humans comprising administering to humans in need thereof an antibactericidally effective amount of a composition of claim 10.--

REMARKS

The amendment is submitted to refer to the PCT application, to remove multiple dependency from the claims and to conform the claims to the American practice.

Respectfully submitted,
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Enclosures: Marked-Up Version of Specification and Claims
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Spherical agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical forms.

---This application is a 371 of PCT/FR00/02393 filed August 28, 2000.---

A subject of the present invention is spherical

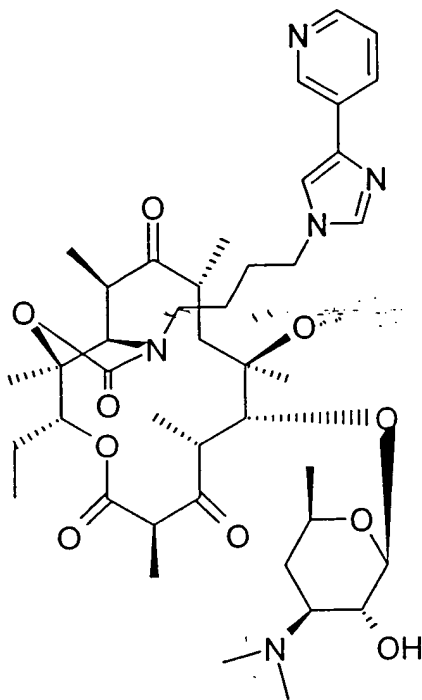
5 agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical forms.

Telithromycin or 11,12-dideoxy-3-de((2,6-dideoxy-3-C-methyl-3-O-methyl-alpha-L-ribohexopyranosyl)oxy)-6-O-methyl-3-oxo-12,11-(oxycarbonyl((4-(4-(3-pyridinyl)-1H-imidazol-1-yl)butyl)imino))-erythromycin is a product endowed with
10 antibiotic properties of structure: ..

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(I)

described and claimed in European Patent 680967.

30 The oral route is a preferred form of administration for this product. Some patients, children in particular, have difficulty in swallowing tablets and capsules and therefore it is desirable to have available other forms of administration such as for example oral suspensions, ready to
35 use or prepared extemporaneously at the time of use.

CONFIRMATION COPY

CLAIMS

- 1) Spherical agglomerates of telithromycin.
- 2) ~~A~~ ^{of} Spherical agglomerates of telithromycin according to
5 claim 1, ~~characterized in that~~ ^{wherein} the size of the particles is
between 30 and 400 microns.
- 3) ~~A~~ ^{of} Spherical agglomerates of telithromycin according to
claim 2, ~~characterized in that~~ ^{wherein} the median size of the
particles is ~~situated~~ between 80 and 150 microns.
- 10 4) ~~A~~ ^{of claim 1} Spherical agglomerates of telithromycin according to any
~~one of claims 1 to 3, characterized in that~~ ^{wherein} the median size
of the particles is ~~situated towards~~ ^{about} 100 microns.
- 5) ~~A~~ ^{of} Process for the preparation of agglomerates according to
any one of ~~claims 1 to 4, characterized in that~~ ^{claim 1, comprising preparing} a suspension
15 of telithromycin crystals ~~is prepared, and these crystals are~~ ^{Coating} then coated with a phase insoluble in telithromycin, ^{from} which telithromycin
progressively crystallizes.
- 6) ~~The~~ ^{of} ~~Preparation~~ process according to claim 5, ~~characterized~~ ^{wherein}
~~in that a solution of telithromycin in acetone is used.~~
- 20 7) ~~The~~ ^{of} Preparation process according to claim 5 ~~or 6,~~
~~characterized in that~~ ^{wherein} the crystallization takes place in an
acetone/isopropyl ether mixture.
- 8) ~~The~~ Preparation process according to any one of claims 5 to
~~7, characterized in that~~ ^{wherein} the crystallization is carried out
25 between -5°C and -15°C.
- 9) Spherical agglomerates of telithromycin as obtained by
the process according to any one of claims 5 to 8.
- 10) Spherical agglomerates of telithromycin according to
claim 9, characterized in that the particle size is comprised
30 between 30 and 400 microns.
- 11) Spherical agglomerates of telithromycin according to claim
10, characterized in that the median size of the particles is
situated between 80 and 150 microns.

12) Spherical agglomerates of telithromycin according to any one of claims 9 to 11, characterized in that the median size of the particles is situated towards 100 microns.

5 13) Use of the spherical agglomerates according to any one of claims 1 to 4 and 9 to 12, characterized in that the spherical agglomerates are surrounded by a layer of polymer in order to obtain the sought galenical form.